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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,524	02/11/2004	Gosse Jan Adema	DX0670KB1B	8025

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EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/777,524	ADEMA ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21 and 23-32* is/are pending in the application.

4a) Of the above claim(s) *30-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21 and 23-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *21 and 23-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/10/06; 10/05/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment 10 January 2006 has been entered in full. Claim 21 is amended. Claims 1-20 and 22 are cancelled.

This application contains claims 30-32 drawn to an invention nonelected without traverse in the communication of 27 April 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21 and 23-29 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

1. The objections to the specification at pg 2-3 of the previous Office Action (12 July 2005) are *withdrawn in part* in view of the amended title (10 January 2006). Please see section on Specification, below.

2. The objection to claim 21 at pg 3 of the previous Office Action (12 July 2005) is *withdrawn* in view of the amended claim (10 January 2006).

3. The rejection of claims 21-29 under 35 U.S.C. § 112, first paragraph (written description) as set forth at pg 8-10 of the previous Office Action (12 July 2005) is *withdrawn* in view of amended claim 21 (10 January 2006).

4. The rejection of claim 21 under 35 U.S.C. § 102(b) as set forth at pg 11 of the previous Office Action (12 July 2005) is *withdrawn* in view of amended claim 21 (10 January 2006).

5. The rejection of claims 21, 23-24, and 29 under 35 U.S.C. § 102(e) as set forth at pg 11-12 of the previous Office Action (12 July 2005) is *withdrawn* in view of amended claim 21 (10 January 2006).

Specification

6. The abstract of the disclosure is objected to because the legal term "said" is used. Applicant is reminded of the proper language and format for an abstract of the disclosure. Correction is required. See MPEP § 608.01(b). This objection is set forth at pg 2 of the previous Office Action (12 July 2005).

7. The disclosure is objected to because of the following informalities:

7a. The use of the trademarks QIAGEN and GENESCREEN have been noted in this application (See pg 84, line 27; pg 85, line 23). They should be capitalized wherever they appear and be accompanied by the generic terminology. The basis for this objection is set forth at pg 2-3 of the previous Office Action (12 July 2005).

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It is noted that in the Response of 10 January 2006, Applicant attempted to amend the specification of the published application. These amendments could not be entered because they are not in accordance with 37 CFR 1.121 (see also MPEP § 714). Specifically, amendments should be made to the specification filed in the case rather than the published application.

Claim Rejections - 35 USC § 101 and 35 U.S.C. § 112, first paragraph

8. Claims 21 and 23-29 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation. The basis for this rejection is set forth for claims 21-29 at pg 3-6 of the previous Office Action (12 July 2005).

The claims are directed to a substantially pure or isolated polypeptide comprising an amino acid sequence of SEQ ID NO: 2. The claims recite a composition comprising the polypeptide and a polypeptide fused to a detection or purification tag. The claims recite a kit comprising the polypeptide. The claims recite that the polypeptide is recombinantly produced.

Applicant's arguments (10 January 2006), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

(i) Applicant states that the Examiner's initial burden is to establish whether it is more likely than not that a skilled artisan would consider an asserted utility to be credible, specific and substantial. Applicant cites *In re Rinehart*, 531 F.2d 1048, 1052; 189 USPQ 143, 147 (CCPA 1976); MPEP §2107.02). Applicant asserts that the Office has not met the burden in articulating a lack of utility because of the credible, specific, and substantial teachings provided in the specification and the state of the art at the relevant point in time.

Applicant's arguments have been fully considered but are not found to be persuasive. In the previous Office Action of 12 July 2005, the Examiner made a *prima facie* showing that the claimed invention lacks utility and provided sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing (see pages 3-6). Essentially, Applicant has

not provided evidence to demonstrate that the FDF03 polynucleotide, polypeptide, and antibody of the instant application are supported by a specific and asserted utility or a well established utility. The Examiner has fully considered all evidence of record and has responded to each substantive element of Applicant's response (see points (ii) -(iv) below). It is noted to Applicant that MPEP § 2107.02 (part VI) also states that "only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained".

(ii) At pg 6 of the response, Applicant contends that the claimed subject matter is useful as a diagnostic and therapeutic target on myeloid cells derived from hematopoietic cells. At pg 7-8 of the response, Applicant asserts that the expression of the present invention both on the mRNA and protein level is restricted to cells of myeloid, e.g., dendritic cell, lineage. Applicant argues that the FDF03 protein is useful to identify cells of myeloid lineage and that it can be used a diagnostic marker for identifying dendritic cells. Applicant points out that antibodies raised against the FDF03 protein have been shown to bind to dendritic cells (specification pg 87, lines 26-27; Fournier et al., J Immunol 165(3): 1197-1209, 2000). Applicant submits that based on the data discussed in the specification and the work by Fournier, an artisan of ordinary skill would more likely than not believe that the diagnostic utility asserted for FDF03 was credible, substantial, and specific. Applicant argues that while a novel protein whose function is unknown may lack utility, it is not a requirement of the statute that its function be known for that protein to have some use which is credible, substantial, and specific. Applicant states that the biological

function of the protein is completely irrelevant to the question of whether the protein iteself is sufficiently useful to justify the granting of a U.S. patent.

Applicant's arguments have been fully considered but are not found to be persuasive. The asserted patentable utility of using FDF03 as a marker to identify dendritic cells is not substantial because the instant application does not disclose the biological role of the FDF03 protein or its significance. Evidence of mere expression on a tissue or cell type is not tantamount to a showing of a functional role of the FDF03 polypeptide. Basic research to determine the functional properties of the claimed protein is still required. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial. It is noted that whereas a scale or a microarray or a gas chromatograph has patentable utility as a research tool, the objects being evaluated with those research tools do not necessarily have patentable utility. In the instant case, the claimed FDF03 polypeptide is not disclosed as having an activity that can be specifically useful. Thus, further research is required to identify or reasonably confirm a specific and substantial utility. See MPEP § 2107.01(I)(C), for example. Such further research requirements make it make it clear that the asserted utility is not yet in currently available form, i.e., it is not substantial. This further experimentation is part of the act of invention and until it has been undertaken, Appellant's claimed invention is incomplete. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct., 1966), wherein the court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", "Congress intended that no patent be granted on a chemical

> compound whose sole "utility" consists of its potential role as an object of use-testing", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

(iii) Applicant provides a declaration by Dr. Joseph Phillips which shows that antibodies against the FDF03 protein were effective to regulate the degranulation of mast cells. At pg 11 of the Response, Applicant argues that in addition to its usefulness as a marker of myeloid-derived cells, the claimed protein is useful as a therapeutic target of compositions which regulate the immune reponses of cells derived from hematopoietic stem cells. Applicant indicates that the specification does not specifically discuss mast cell regulation. Applicant states that the specification does recognize that the disclosed proteins play a role in the regulation of immunological responses produced from immune cells derived from hematopoietic stem cells. Applicant concludes that because mast cell degranulation is an immunological response that can be inhibited by antibodies against the claimed protein, evidence demonstrating an impact of antibodies against the claimed protein supports the asserted therapeutic use of this protein.

Applicant's arguments have been fully considered but are not found to persuasive. The declaration of Dr. Joseph Phillips filed under 37 CFR 1.132 filed 10 January 2006 is insufficient to overcome the rejection of claims 21 and 23-29 based upon lack of utility and/or inoperativeness under 35 U.S.C. 101 as set forth in the last Office action. Specifically, the declaration of Dr. Phillips states that "results of these experiments showed that agonist antibodies raised against FDF03 could prevent mast cell degranulation, thus impairing the inflammatory cascade associated with mast cell function" (pg 3, for example). However, this asserted utility for antibodies against FDF03 (to inhibit the degranulation of mast cells, thus preventing mast cell mediated inflammation) is not supported by the instant specification as filed. For utility to be

"well established", it must be specific and substantial. Furthermore, the assertion that FDF03 plays a role in the regulation of immunological responses produced from immune cells derived from hematopoietic cells is not not specific since many other proteins also play a role in the regulation of immunological responses produced from immune cells. Regarding the utilization of FDF03 for therapeutic purposes, the specification provides little guidance indicating which specific disorders or conditions are associated with altered levels or forms of the FDF03 polypeptide. The specification discloses nothing about the normal levels of expression of the polypeptide. Significant further experimentation would be required of the skilled artisan to identify individuals with disorders or conditions are associated with altered levels or forms of the FDF03 polypeptide. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

(iv) At pg 8-9 of the response, Applicant asserts that FDF03 is an inhibitory receptor and that its function as an inhibitory receptor is recognized in the art. Applicant points out that the assertion is made based on research papers published by those of ordinary skill in the art which have referenced the work by Fournier et al. (J Immunol 165(3): 1197-1209, 2000). Applicant briefly reviews the post-filing date references submitted as Exhibits B-G. Applicant argues that more than an adequate amount of data has been provided to the Office which demonstrates the useful role of the FDF03 protein as a diagnostic marker on monocytes.

Applicant's arguments have been fully considered but are not found to be persuasive. The specification of the instant application only discloses that the claimed FDF03 polypeptide comprising the amino acid sequence of SEQ ID NO: 2 is isolated from activated monocytes and

is a type I transmembrane protein with an Ig-like extracellular portion (pg 3, lines 3-7). The specification does not teach any significance or functional characteristics of the FDF03 polynucleotide (SEQ ID NO: 1) or polypeptide (SEQ ID NO: 2). The specification at the time of filing does not disclose that FDF03 is an inhibitory receptor or disclose its physiological activity. Although the post-filing date references, which study FDF03, are interesting, they clearly indicate that at the time of filing, further characterization of FDF03 was required and Applicant's invention was incomplete. Applicant has not established a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention.

9. Claims 21 and 23-29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The basis for this rejection is set forth for claims 21-29 at pg 6 of the previous Office Action (12 July 2005).

Applicant's arguments (10 January 2006), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

Specifically, since Applicant has not provided evidence to demonstrate that the FDF03 polypeptide of SEQ ID NO: 2 has a specific and substantial asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BEB
Art Unit 1647
31 March 2006

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